

Thursday  
March 2, 2000

Dear FDA,

Enclosed is Article which I hope you will ~~set~~ <sup>see</sup> and approve. I know I am a good candidate for such a device. My husband has a hearing aid and is on the dresser not in his ear. They don't work that good, try it.

Please give this your most serious thoughts, because I see nothing wrong with the concept of amplification, - have one on phone it works good.

I have also written to you about avarulo plastic I had done in 1990.

This procedure saved me suffering and cost which would have halved Medicare's expenses. I was very lucky to have a Cardiologist who did it free because he cared.

Please help us by approving practical methods and solutions to our lives.

Yours Truly  
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# Maine company offering alternative hearing device

Its makers say it's not a hearing aid, it's more like an inexpensive amplifier.

SCARBOROUGH, Maine (AP) — A company that says its "hearing enhancement device" is too mild to be described as a traditional hearing aid is lobbying federal regulators to allow the device to be sold over the counter.

Edouard Gauthier calls his device "reading glasses for the ears" because it is so mild he thinks it should be marketed like reading glasses.

But that would require changes in the way the Food and Drug Administration defines hearing aids. People who support the current standard say a hearing specialist should be involved in any decision on the use of such devices.

"We don't recommend this kind of hearing unit because it's just amplification," said Michele Dalessio, spokeswoman for Dial-A-Hearing Screening Test, an audiologist-funded organization that tests people's hearing over the phone and directs them to audiologists.

When people buy without the help of a hearing specialist, they don't get exactly what they need or follow-up support, she said.

Gauthier believes his new instrument, with printed warnings advising people to see an ear doctor or audiologist, will actually get people to seek the help they might not get otherwise.

"Only about two out of 10 people who should wear hearing aids actually do," said Gauthier. "Because of the cost, people thinking they might need some hearing help don't take the step."


Formerly based in Philadel-

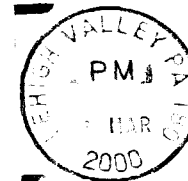
phia, Audio D bought out financially troubled Finetone Hearing of Scarborough last April and moved all its operations here. Audio D now has 27 employees, producing 150 to 200 hearing devices per week.

Audio D plans to start selling its new device over the Internet this week, and through audiologists soon. But it will need to see if the FDA changes its definitions before the device can be stocked on pharmacy shelves.

Called Simplicity, the device costs \$195, compared with \$600 to \$2,000 or more for regular hearing aids. It is among a handful of "entry level" hearing devices — less expensive and less powerful than regular hearing aids.

Unlike typical hearing aids, which are molded to the user's ear canal, Simplicity comes with a foam tip that can be shaped to almost any ear.

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